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Federal Agencies

January 26, 2005

WRITER'S DIRECT NUMBER:
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Mail Stop Amendment

Re: U.S. Utility Patent Application
Appl. No. 10/622,088; Filed: July 18, 2003
For: **Viral Vectors Containing Recombination Sites**
Inventors: Bennett *et al.*
Our Ref: 0942.5450007/RWE/BJD/SJE

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Second Supplemental Information Disclosure Statement;
2. Form PTO-1449 (23 sheets citing 102 documents);
3. 78 documents cited in Form PTO-1449 (attached); and
4. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Brian J. Del Buono
Attorney for Applicants
Registration No. 42,473

BJD/SJE/lam
Enclosures

354317.1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Bennett *et al.*

Appl. No.: 10/622,088

Filed: July 18, 2003

For: **Viral Vectors Containing
Recombination Sites**



Confirmation No.: 1853

Art Unit: 1653

Examiner: Brown, Timothy M.

Atty. Docket: 0942.5450007/RWE/BJD/SJE

Second Supplemental Information Disclosure Statement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450
Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

The numbering on this Second Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' First Supplemental Information Disclosure Statement filed May 21, 2004, in connection with the above-captioned application.

Copies of documents **AA16-AK16** and **AA17-AE17** are not provided in accordance with the Changes To Support Implementation of the United States Patent and Trademark Office 21st Century Strategic Plan, effective October 21, 2004, which states "section 1.98(a)(2)(i) is amended to eliminate the requirement in paragraph (a)(2)(i) for a copy of each U.S. patent or U.S. patent application publication listed in an IDS in a patent application regardless of the filing date of the application."

Copies of documents **AR200-AT200**, **AR201-AT201** and **AR202-AS202** are not provided in accordance with the U.S. Patent and Trademark Office OG notice of October 19, 2004, which states: "the requirement in 37 C.F.R. § 1.98(a)(2)(iii) for a legible copy of the specification, including the claims, and drawings of each cited pending U.S. patent application (or portion of the application which caused it to be listed) is *sua sponte* waived where the cited pending application is stored in the USPTO's IFW system."

A copy of each other document is provided.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following, in regards to non-English language documents **AM11** and **AN11** cited on Form PTO 1449:

Document **AM11**, French Patent Publication No. FR 2 670 502, is in the French language. Document **AN11**, PCT Patent Publication No. WO 92/10577, is in the French language. An unverified English language abstract of documents **AM11** and **AN11** is attached as document **AT196**.

The Examiner's attention is directed to the following co-pending U.S. Patent Applications, which are directed to related technical subject matter:

U.S. Patent Application No. 09/438,358, Gerard *et al.*, filed November 12, 1999 and cited herewith as document **AR200**;

U.S. Patent Application No. 10/633,690, Byrd *et al.*, filed August 5, 2003 and cited herewith as document **AS200**;

U.S. Patent Application No. 10/792,035, Chesnut *et al.*, filed March 4, 2004 and cited herewith as document **AT200**;

U.S. Patent Application No. 10/877,952, Welch *et al.*, filed July 28, 2004 and cited herewith as document **AR201**;

U.S. Patent Application No. 10/913,501, Chesnut *et al.*, filed August 9, 2004 and cited herewith as document **AS201**;

U.S. Patent Application No. 10/921,265, Hartley *et al.*, filed August 19, 2004 and cited herewith as document **AT201**;

U.S. Patent Application No. 10/970,635 , Hanson, filed October 22, 2004 and cited herewith as document **AR202**; and

U.S. Patent Application No. 11/000,371, Chesnut *et al.*, filed December 1, 2004 and cited herewith as document **AS202**.

In accordance with the recent Federal Circuit decision in *Dayco Prods., Inc. v. Total Containment, Inc.* 329 F.3d 1358 (Fed. Cir. 2003), Applicants submit herewith Office Actions from related copending applications as Documents **AR197-AT199**.

The identification of these U.S. Patent Applications and Office Actions are not to be construed as a waiver of secrecy as to these applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and Office Actions, and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached Form PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Second Supplemental Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed Form PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read "Brian J. Del Buono", with a large, sweeping flourish at the end.

Brian J. Del Buono
Attorney for Applicants
Registration No. 42,473

Date: January 26, 2005
1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

FORM PTO-1449

SECOND SUPPLEMENTAL
INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
0942.5450007/RWE/BJD/SJE

APPLICATION NO.
10/622,088

APPLICANT(S)
Bennett *et al.*

FILING DATE
July 18, 2003

ART UNIT
1653

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA16	4,808,537	02/28/1989	Stroman <i>et al.</i>			10/30/1984
	AB16	4,855,231	08/08/1989	Stroman <i>et al.</i>			09/25/1985
	AC16	4,959,217	09/25/1990	Sanders <i>et al.</i>			05/22/1986
	AD16	5,451,513	09/19/1995	Maliga <i>et al.</i>			08/25/1993
	AE16	5,654,182	08/05/1997	Wahl <i>et al.</i>			06/07/1995
	AF16	2002/0106797	08/08/2002	Miles <i>et al.</i>			03/12/2001
	AG16	2003/0153055	08/14/2003	Miles <i>et al.</i>			02/20/2003
	AH16	2003/0157716	08/21/2003	Hartley <i>et al.</i>			11/02/2001
	AI16	2003/0176644	09/18/2003	Byrd <i>et al.</i>			02/07/2002
	AJ16	2003/0220249	11/27/2003	Hackett <i>et al.</i>			02/07/2003
	AK16	2004/0040053	02/26/2004	Nomura <i>et al.</i>			11/22/2002

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM11	FR 2 670 502	06/16/1992	France			Yes X No
	AN11	WO 92/10577	06/25/1992	WIPO			Yes X No
	AO11	WO 94/20604	09/15/1994	WIPO			Yes No
	AP11	WO 00/29000	05/25/2000	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR		
	AS		
	AT	<u>180</u>	Agah, R., <i>et al.</i> , "Gene Recombination in Postmitotic Cells. Targeted Expression of Cre Recombinase Provokes Cardiac-restricted, Site-specific Rearrangement in Adult Ventricular Muscle In Vivo," <i>J. Clin. Invest.</i> 100:169-179, The American Society for Clinical Investigation, Inc. (July 1997)

EXAMINER

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	AA17	2004/0171156	09/02/2004	Hartley <i>et al.</i>			04/02/2004
	AB17	2004/0171157	09/02/2004	Hartley <i>et al.</i>			04/08/2004
	AC17	2004/0219516	11/04/2004	Bennett <i>et al.</i>			07/18/2003
	AD17	2004/0219673	11/04/2004	Hartley <i>et al.</i>			03/10/2004
	AE17	2004/0253631	12/16/2004	Hartley <i>et al.</i>			07/19/2004
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL12	WO 00/52027	09/08/2000	WIPO			Yes No
	AM12	WO 00/52141	09/08/2000	WIPO			Yes No
	AN12	WO 01/25466	04/12/2001	WIPO			Yes No
	AO12	WO 01/31039	05/03/2001	WIPO			Yes No
	AP12	WO 01/42509	06/14/2001	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>181</u>	Ball, C.A., and Johnson, R.C., "Efficient Excision of Phage λ from the <i>Escherichia coli</i> Chromosome Requires the Fis Protein," <i>J. Bacteriol.</i> 173: 4027-4031, American Society for Microbiology (July 1991)
	AS	<u>181</u>	Benoist, C. and Chambon, P., "In vivo sequence requirements of the SV40 early promoter region," <i>Nature</i> 290:304-310, Macmillan Journals, Ltd. (1981)
	AT	<u>181</u>	Botstein, D., <i>et al.</i> , "Making Mutations <u>In Vitro</u> and Putting Them Back Into Yeast," in <i>From Gene to Protein: Translation into Biotechnology</i> , Ahmad, F., <i>et al.</i> , eds., Academic Press, New York, NY, pp. 265-274 (1982)

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL13	WO 02/00875	01/03/2002	WIPO			Yes No
	AM13	WO 02/16594	02/28/2002	WIPO			Yes No
	AN13	WO 02/46372	06/13/2002	WIPO			Yes No
	AO13	WO 02/061034	08/08/2002	WIPO			Yes No
	AP13	WO 02/62957	08/15/2002	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>182</u>	Broach, J.R., "The Yeast Plasmid 2 μ Circle," <i>Cell</i> 28:203-204, MIT (1982)
	AS	<u>182</u>	Cenatiempo, Y., "Prokaryotic gene expression <i>in vitro</i> : transcription-translation coupled systems," <i>Biochimie</i> 68:505-515, Elsevier (1986)
	AT	<u>182</u>	Christiansen, B., <i>et al.</i> , "A Resolvase-Like Protein Is Required for the Site-Specific Integration of the Temperate Lactococcal Bacteriophage TP901-1," <i>J. Bacteriol.</i> 178:5164-5173, American Society for Microbiology (September 1996)

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL14	WO 02/86144	10/31/2002	WIPO			Yes No
	AM14	WO 02/095055	11/28/2002	WIPO			Yes No
	AN14	WO 03/044207	05/30/2003	WIPO			Yes No
	AO14	WO 03/103600	12/18/2003	WIPO			Yes No
	AP14	WO 04/009768	01/29/2004	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>183</u>	Crellin, P.K. and Rood, J.I., "The Resolvase/Invertase Domain of the Site-Specific Recombinase TnpX Is Functional and Recognizes a Target Sequence That Resembles the Junction of the Circular Form of the <i>Clostridium perfringens</i> Transposon Tn4451," <i>J. Bacteriol.</i> 179:5148-5156, American Society for Microbiology (August 1997)
	AS	<u>183</u>	Ferrin, L.J. and Camerini-Otero, R.D., "Sequence-specific ligation of DNA using RecA protein," <i>Proc. Natl. Acad. Sci. USA</i> 95:2152-2157, National Academy of Sciences (March 1998)
	AT	<u>183</u>	Golic, K.G. and Golic, M.M., "Engineering the Drosophila Genome: Chromosome Rearrangements by Design," <i>Genetics</i> 144:1693-1711, The Genetics Society of America (1996)

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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL15	WO 04/013290	02/12/2004	WIPO			Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>184</u>	Gottesman, S., "Bacterial Regulation: Global Regulatory Networks," <i>Ann. Rev. Genet.</i> 18:415-441, Annual Reviews, Inc. (1984)
	AS	<u>184</u>	Guo, F., <i>et al.</i> , "Structure of Cre recombinase complexed with DNA in a site-specific recombination synapse," <i>Nature</i> 389:40-46, Nature Publishing Group (September 1997)
	AT	<u>184</u>	Hallet, B. and Sherratt, D.J., "Transposition and site-specific recombination: adapting DNA cut-and-paste mechanisms to a variety of genetic rearrangements," <i>FEMS Microbiol. Rev.</i> 21:157-178, Elsevier Science B.V. (September 1997)

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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>185</u>	Hamer, D.H. and Walling, M., "Regulation <i>In Vivo</i> of a Cloned Mammalian Gene: Cadmium Induces the Transcription of a Mouse Metallothionein Gene in SV40 Vectors," <i>J. Mol. Appl. Genet.</i> 1:273-288, Raven Press (1982)
	AS	<u>185</u>	Hanks, S.K. and Hunter, T., "The eukaryotic protein kinase superfamily: kinase (catalytic) domain structure and classification," <i>FASEB J.</i> 9:576-596, The Federation of American Societies for Experimental Biology (May 1995)
	AT	<u>185</u>	Hartley, J.L., <i>et al.</i> , "DNA Cloning Using In Vitro Site-Specific Recombination," <i>Genome Res.</i> 10:1788-1795, Cold Spring Harbor Laboratory Press (November 2000)

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	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>186</u>	Huang, L-C., <i>et al.</i> , "Convenient and Reversible Site-Specific Targeting of Exogenous DNA into a Bacterial Chromosome by Use of the FLP Recombinase: the FLIRT System," <i>J. Bacteriol.</i> 179:6076-6083, American Society for Microbiology (October 1997)
	AS	<u>186</u>	John, Jr., J.F. and Twitty, J.A., "Plasmids as Epidemiologic Markers in Nosocomial Gram-Negative Bacilli: Experience at a University and Review of the Literature," <i>Rev. Infect. Dis.</i> 8:693-704, University of Chicago (1986)
	AT	<u>186</u>	Johnston, S.A. and Hopper, J.E., "Isolation of the yeast regulatory gene <i>GAL4</i> and analysis of its dosage effects on the galactose/melibiose regulon," <i>Proc. Natl. Acad. Sci. USA</i> 79:6971-6975, National Academy of Sciences (1982)

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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

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	AR	<u>187</u>	Kendall, K.J. and Cohen, S.N., "Plasmid Transfer in <i>Streptomyces lividans</i> : Identification of a <i>kil-kor</i> System Associated with the Transfer Region of pIJ101," <i>J. Bacteriol.</i> 169:4177-4183, American Society for Microbiology (1987)
	AS	<u>187</u>	Lenski, R.E., <i>et al.</i> , "Genetic Analysis of a Plasmid-Encoded, Host Genotype-Specific Enhancement of Bacterial Fitness," <i>J. Bacteriol.</i> 176:3140-3147, American Society For Microbiology (1994)
	AT	<u>187</u>	Lyznik, L.A., <i>et al.</i> , "Activity of yeast FLP recombinase in maize and rice protoplasts," <i>Nucleic Acids Res.</i> 21:969-975, Oxford University Press (1993)

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**SECOND SUPPLEMENTAL
INFORMATION DISCLOSURE STATEMENT**

ATTY. DOCKET NO.
0942.5450007/RWE/BJD/SJE

APPLICATION NO.
10/622,088

APPLICANT(S)
Bennett *et al.*

FILING DATE
July 18, 2003

ART UNIT
1653

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
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	AR	<u>193</u>	Shuman, S., "Site-specific Interaction of Vaccinia Virus Topoisomerase I with Duplex DNA. Minimal DNA Substrate for Strand Cleavage <i>In Vitro</i> ," <i>J. Biol. Chem.</i> 266:11372-11379, The American Society for Biochemistry and Molecular Biology, Inc. (1991)
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	AS	<u>197</u>	Office Action for U.S. Patent Application No. 09/432,085, mailed on July 16, 2004
	AT	<u>197</u>	Office Action for U.S. Patent Application No. 10/058,291, mailed on September 22, 2004

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	AM						Yes
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	AN						Yes
							No
	AO						Yes
							No
	AP						Yes
							No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>202</u>	U.S. Patent Application No.10/970,635, Hanson, filed October 22, 2004 (NOT PUBLISHED)
	AS	<u>202</u>	U.S. Patent Application No.11/000,371, Chesnut <i>et al.</i> , filed December 1, 2004 (NOT PUBLISHED)
	AT		
EXAMINER			
DATE CONSIDERED			

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.